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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,033	06/27/2001	Genichi Kakefuda		3401

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/893,033	KAKEFUDA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 July 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-83 is/are pending in the application.
- 4a) Of the above claim(s) 11-37, 49-51 and 63-83 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 38-48 and 52-62 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 June 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### **1. *Election***

Applicant's election with traverse of Group III (claims 38-48 & 52-62) drawn to polynucleotides of SEQ ID NO: 6 & 17, filed 7.6.2004 is acknowledged. The traversal is on the ground(s) that examinations of all the 9 groups would not be undue burden because of the close technological relationship. This is not found persuasive because depending upon the restricted group (I through IX) being examined, additional classes/subclasses have to be searched as indicated in the restriction requirement. Sequence(s) search from a variety of sequence data bases will have to be conducted depending upon the elected group. This additional searching would therefore involve undue burden to the Examiner. The requirement is still deemed proper and is therefore made FINAL.

### **Claims withdrawn :**

Claims 11-37, 49-51 & 63-83 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed.

### **2. *Continuation of prior application***

This application filed under 35 USC 119(e) lacks the necessary reference to the prior application. This application claims the benefit of US Provisional Application No. 06/214,705 , filed 06.27.2000, should be entered following the title of the invention or as the first sentence of the specification. Also, the present status of all parent applications should be included.

### **3. *Abstract***

\*This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

\*The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words [in length since the space provided for the abstract on the computer tape by the printer is limited]. The form and legal phraseology often used in patent claims, such as "means" and "said", should be avoided in the abstract. The abstract should sufficiently describe the disclosure to assist readers in deciding whether there is a need for consulting the full patent text for details. MPEP 608.01(b).

The current abstract is in two paragraphs.

4. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, pages 28 & 40) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

6. Claims 38-48 & 52-62 are pending and under consideration in this examination.

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7. Confusion about the definition of 'AHAS' : Applicants' specification on page 7, line 13, define 'ahas' as 'acetohydroxyacid synthase'. However, Applicants' abstract and specification on page 9, line 11, define 'ahas' as 'acetolactate synthase'. Which one is it ? Clarification is requested.

8. ***Claim Rejections - 35 USC §112*** (first paragraph)

Claims 38-40, 42-48, 52-54 & 56-62 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for *Synechocystis* PCC 6803 polynucleotides of SEQ ID NO: 6 and 17 encoding AHAS large and small subunits respectively, does not reasonably provide enablement for any polynucleotide encoding AHAS large and small subunits from any cyanobacterium [including *Synechocystis*, *Anabaena*, *Thermosynechococcus elongatus* and *Spirulina* among others] (claims 38-39, 52-53), or wherein the AHAS large/small subunit gene confers resistance to a herbicide (claims 40, 54), or a vector comprising such a polynucleotide (claims 42, 48, 56, 62), or a nuclear genome (complete set of genetic material present in the nucleus) comprising the vector (claims 43, 57), or a plastome (the genetic compliment of a plastid) comprising the vector (claims 44, 58), or a transgenic plant produced from the transformation of the replicable expression vector or its progeny (claims 45-47, 59-61). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) [*Ex parte Forman* (230 USPQ 546 (Bd. Pat. App. & Int. 1986)). The Wands factors are: (a) the quantity of experimentation necessary, (b) the

amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary].

The specification, however, only discloses the full length sequence of a polynucleotide of SEQ ID NO: 6 & 17 encoding AHAS large and small subunits respectively. There is no disclosure or description of other polynucleotide(s) encoding the AHAS large and small subunits from other sources, or even from *Synechocystis*, and its further transformation into a replicable vector, nuclear genome, plastome or a transgenic plant. Despite knowledge in the art for the isolation of homologous genes from a variety of sources, given the structure and function of a single gene (or polynucleotides), the claims encompass enormous numbers of polynucleotides with no known structural similarity to aid one skilled in the art selectively isolate other AHAS encoding polynucleotide(s) from any cyanobacterium or *Synechocystis*.

The specification does not support the broad scope of the claims which encompass any polynucleotide encoding AHAS large and small subunits from any cyanobacterium, because the specification does not establish: (A) regions of the protein structure which may be conserved without effecting AHAS activity; (B) the general occurrence of AHAS; (C) a rational and predictable scheme for isolating any AHAS from any cyanobacterium with an expectation of obtaining the desired biological

function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Without such guidance, the experimentation left to those skilled in the art is undue.

**9. 35 U.S.C. § 112, first paragraph (Written Description)**

Claims 38-40, 42-48, 52-54 & 56-62 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 38-40, 42-48, 52-54 & 56-62 are directed to any polynucleotide encoding AHAS large and small subunits from any cyanobacterium [including *Synechocystis*, *Anabaena*, *Thermosynechococcus elongates* and *Spirulina* among others] (claims 38-39, 52-53), or wherein the AHAS large/small subunit gene confers resistance to a herbicide (claims 40, 54), or a vector comprising such a polynucleotide (claims 42, 48, 56, 62), or a nuclear genome (complete set of genetic material present in the nucleus) comprising the vector (claims 43, 57), or a plastome (the genetic compliment of a plastid) comprising the vector (claims 44, 58), or a transgenic plant produced from the transformation of the replicable expression vector or its progeny (claims 45-47, 59-61), the claimed genus.

The specification, however, only provides a single representative species of *Synechocystis* PCC 6803 polynucleotide(s) of SEQ ID NO: 6 and 17 encoding AHAS large and small subunits respectively. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species to other species where such sequences are conserved in order to establish a relationship among species and have AHAS activity.

Applicants claims to 'a nuclear genome' (complete set of genetic material present in the nucleus) or a plastome (the genetic compliment of a plastid) comprising any polynucleotide from any cyanobacterium and encoding AHAS small and large subunits also lack structure to function/activity relationship.

The specification also fails to describe additional representative species of these nucleic acids encoding the large and small subunits of AHAS by any identifying structural characteristics other than the properties or activity recited in claims, for which no predictability of structure is apparent. Given this lack of additional representative species, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

10. ***Claim Rejections - 35 USC §112*** (second paragraph)

Claims 38-48 & 52-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38 & 52, line 2, recite 'AHAS', which is not a common abbreviation and must be clearly defined (spelled out) at first use, and which may be abbreviated subsequently. As pointed in item 7, above : Applicants' specification on page 7, line 13, define 'ahas' as 'acetohydroxyacid synthase'. However, Applicants' abstract and specification on page 9, line 11, define 'ahas' as 'acetolactate synthase', which is confusing and indefinite.

Claims 39-48 & 53-62 are included in the rejection for failing to correct the defect present in the base claim(s).

11. Claim 39, line 2-3, recites 'cyanobacterium is extracted' ...from *Synechocystis*...'. The claim is indefinite in the use of the phrase 'extracted from' as well the meaning of the phrase. The phrase 'extracted from' gives one the impression that the cells are squeezed to extract out the cyanobacterium. Use of 'derived from' is suggested. Further, it is unclear how a entire class of cyanobacterium be derived from [or extracted from] a species such 'Synechocystis PCC 6803. Clarification is required. Perhaps deleting the phrase 'extracted from' will straighten the meaning of the claim as well as the 'indefiniteness'.

12. Similarly, in claim 53, line 2, inserting 'is' after 'cyanobacterium' is suggested to correct the grammar.

13. **Priority:** In evaluating the prior art, Applicants were deemed to be entitled to an **effective filing date of 6.27.2001**, the filing date of this application [09/893,033]. The priority document was examined from the prior application, serial number, 60/214,705, and was determined to be lacking an enabling disclosure with respect to the claimed invention. The instant application is therefore not entitled to an effective filing date earlier than 6.27.2000.

Applicants' provisional application 60/214,705, do not contain any sequence listing, and SEQ ID Nos. 6 & 17 are not disclosed in the priority document. Further, Figures 11-15, describing the AHAS gene constructs, are present in the instant application, but are lacking in the provisional application.

14. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38 & 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Milano et al. [J. Gen. Microbiol. (1992), 138 : 1399-1408, **IDS**]. Milano et al. teach molecular characterization of genes encoding acetohydroxy acid synthase from cyanobacterium *Spirulina platensis*. Only the genes encoding the large subunits [having the catalytic activity] or isozymes are described. Vector and *E.coli*. expression system(s) are also taught. The small subunits were not identified. The reference teaches all the claim limitations, and therefore anticipates the claims. [see abstract, MM, R & D; and the attached sequence search alignment]

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group in the Technology Center is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.



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